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Sterile Erythromycin Lactobionate

» Sterile Erythromycin Lactobionate has a potency equivalent to not less than 525 µg of erythromycin ($C_{37}H_{67}NO_{13}$) per mg, calculated on the anhydrous basis. In addition, where packaged for dispensing, it contains the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled amount of erythromycin ($C_{37}H_{67}NO_{13}$).

Packaging and storage—Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging, Packaging for constitution](#).

USP REFERENCE STANDARDS (11)—

[USP Erythromycin RS](#)

[USP Erythromycin Lactobionate RS](#)

Change to read:

Identification, ▲[SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#)▲ (CN 1-May-2020) : the specimen and the Reference Standard being previously dried in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours.

BACTERIAL ENDOTOXINS TEST (85)—It contains not more than 1.0 USP Endotoxin Unit per mg of erythromycin.

STERILITY TESTS (71)—It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

pH (791): between 6.5 and 7.5, in a solution containing the equivalent of 50 mg of erythromycin per mL.

WATER DETERMINATION, Method I (921): not more than 5.0%.

PARTICULATE MATTER IN INJECTIONS (788): meets the requirements for small-volume injections when it is diluted with filtered water to a concentration of not more than 5 mg of erythromycin per mL before the test is performed.

RESIDUE ON IGNITION (281): not more than 2.0%, the charred residue being moistened with 2 mL of nitric acid and 5 drops of sulfuric acid.

Other requirements—Where packaged for dispensing, it meets the requirements for [Uniformity of Dosage Units \(905\)](#) and for [Labeling \(7\)](#).

[Labels and Labeling for Injectable Products](#).

Assay—

Standard preparation—Prepare as directed for erythromycin under [Antibiotics—Microbial Assays \(81\)](#).

Assay preparation 1—Dissolve an accurately weighed quantity of Sterile Erythromycin Lactobionate quantitatively in methanol to obtain a stock solution containing the equivalent of about 10 mg of erythromycin per mL. Dilute this stock solution quantitatively with *Buffer B.3* (see [Antibiotics—Microbial Assays \(81\)](#), [Media and Solutions, Solutions, Buffers](#)) to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

Assay preparation 2 (where it is packaged for dispensing and is represented as being in a single-dose container)—Constitute Sterile Erythromycin Lactobionate in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute quantitatively with *Buffer B.3* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

Assay preparation 3 (where the label states the quantity of erythromycin in a given volume of constituted solution)—Constitute 1 container of Sterile Erythromycin Lactobionate in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Dilute an accurately measured volume of the constituted solution quantitatively with *Buffer B.3* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

Procedure—Proceed as directed for erythromycin under [Antibiotics—Microbial Assays \(81\)](#).

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
STERILE ERYTHROMYCIN LACTOBIONATE	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: [Chromatographic Database](#)

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